
Zoll and Welch Allyn recall AEDs

Zoll and Welch Allyn issued separate recalls for external defibrillators in recent months. Both are Class I recalls, the most severe type of FDA recall, meaning there is a potential for serious injury or death.

Zoll Medical recalled about 180,000 Zoll AED Plus devices manufactured prior to February 12, 2009. The AEDs involved in the recall carry serial numbers below "X __ _200000." Zoll reports two incidents in which the patient died when the device failed to deliver a shock. According to the company, a Zoll AED Plus may prompt users to "change batteries" during use following a long period (typically greater than four years) without use and fail to deliver a shock. In some instances turning the device off completely, waiting for at least ten seconds for the unit to re-set and then turning it back on has restored the unit's ability to deliver defibrillation therapy as intended. The problem is with the software that tests the batteries and will not be corrected by installing new batteries. Zoll is asking users to

download free software at www.ZOLLAEDPlusbatteryhelp.com and then to check the batteries using the new software. Change the batteries if prompted to do so by the device.

For now, Zoll is not recommending the removal of any AED Plus defibrillators from service. Affected units will be capable of detecting defective batteries during the self-test after the recommended software upgrade. Once the software upgrade has been installed, batteries on the device should be changed every three years. If the Zoll AED Plus defibrillator shuts off or otherwise malfunctions during patient therapy, continued CPR is recommended. The FDA website is www.fda.gov/cdrh/recalls/recall-021209b.html. You can reach Zoll by phone at (800) 348-9011 or (978) 421-9460.

Welch Allyn recalled about 14,000 external defibrillators after 39 incidents reported, including two that involved patient deaths. The recall includes AED 10 and MRL JumpStart external defibrillators made between October 3, 2002,



and January 25, 2007. The Beaverton, Oregon, company says there is a chance the devices, available through prescription, may produce low-energy shock, shut down unexpectedly or be susceptible to electromagnetic noise interference. The issues might prevent defibrillation of a patient in cardiac arrest and could lead to death, the company said in a statement. Welch Allyn had received notice of 20 instances of low-energy shock, eight instances of electromagnetic noise interference, and 11 instances of the device unexpectedly shutting down. For more information, go to the Welch Allyn recall website at www.welchallyn.com/support/customer/AED_lookup.jsp or call them at (800) 535-6663. — *Kelly Harrell*